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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/617,208	07/10/2003	Alexander N. Glazer	B00-016-2	3116
23379	7590	08/17/2006	EXAMINER	
RICHARD ARON OSMAN SCIENCE AND TECHNOLOGY LAW GROUP 242 AVE VISTA DEL OCEANO SAN CLEMENTE, CA 92672			KAM, CHIH MIN	
			ART UNIT	PAPER NUMBER
			1656	

DATE MAILED: 08/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/617,208

Applicant(s)

GLAZER ET AL.

Examiner

Chih-Min Kam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 and 19 is/are rejected.
- 7) ☒ Claim(s) 14-18 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Claims 1-19 are pending.

Applicants' amendment filed June 7, 2006 is acknowledged. Applicants' response has been fully considered. Claims 1, 12 and 13 have been amended, and claims 20-22 have been cancelled. Therefore, claims 1-19 are examined.

Withdrawn Claim Rejections - 35 USC § 112

2. The previous rejection of claims 12, 13 and 20-22 under 35 U.S.C. 112, second paragraph, is withdrawn in view of applicants' amendment to the claims, applicants' cancellation of the claim, and applicants' response at page 4 in the amendment filed June 7, 2006.

Withdrawn Claim Rejections - 35 USC § 102

3. The previous rejection of claim 20 under 35 U.S.C. 102(b) as being anticipated by Colleen Mary Toole (Dissertation; UMI microfilm 9839498), is withdrawn in view of applicants' cancellation of the claim in the amendment filed June 7, 2006.

Withdrawn Claim Rejections-Obviousness Type Double Patenting

4. The previous rejection of claims 20-22 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 11-18 of U. S. Patent 6,649,376, is withdrawn in view of applicants' cancellation of the claim, and applicants' response at page 5 in the amendment filed June 7, 2006.

New Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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5. Claims 5-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 5-7 are indefinite because the claims do not further limit the independent claim, claim 1.

Maintained Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-4, 6, 8-13 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Colleen Mary Toole (Dissertation; UMI microfilm 9839498, available on December 14, 1998 according to Proquest).

Toole teaches the construction and expression of the CpcB strep-tag protein incorporated in a phycobilisome assembly in *E.coli* (Chapter III, pages 151-167), where the phycobilisomes from ST13 lysates are purified using a streptavidin column eluted with a buffer (pages 54-55; page 161; claims 1, 2 and 4), and where a small peptide sequence SAWRHPQRGG, a biotin mimic that binds to streptavidin, was added to the carboxyl terminal of the CpcB subunit with a peptide linker (Fig. 27; claim 6) and used as an affinity tag for the purification of biliprotein subunits on the streptavidin columns. A construct encoding phycocyanin β subunit fused to the strep-tag was prepared and introduced into cyanobacterial transformation vector creating pCBST13 (see Fig. 25; page 152), and expression and assembly of CpcB-St was carried out in

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strain 4R (page 155), where phycobilisomes isolated from ST13 contain CpcA and CpcBst (Fig. 26; claims 3, 8-11, 19). The reference also indicates the whole-cell absorbance spectra for R20 (positive control), 4R (negative control, PC-minus) and ST13 cultures showed that the PC content in ST13 (as measured by the signal near 625 nm) was clearly increased relative to that in 4R but was less than the PC level of R20, and energy transfer from PC to AP in ST13 was similar to R20 cells with prominent emission in the 685 nm region and minimal fluorescence near 638 nm (page 155, claims 12-13).

While claim 1 has been amended to the fusion protein further comprises (a) a specific binding moiety selected from a streptavidin biotin-binding moiety, a biotinylated or biotinylatable moiety, and an antigen binding immunoglobulin moiety; or (b) a protease cleavage site between the displayed domain and the phycobiliprotein domain, the claim does not indicate the functional displayed domain is different and separate from the specific binding moiety. Since the reference teaches the fusion protein of phycocyanin β subunit and the strep-tag, and the strep-tag can be a functional displayed domain and also a streptavidin biotin-binding moiety, thus the reference anticipates the claimed invention.

Response to Arguments

Applicants indicate the Proquest letter, dated Jan 16, 2006 does not allege facts evidencing that the dissertation was in fact published prior to Dec 21, 1998. There is no evidence of record indicating the cited Toole dissertation was available to the interested public prior to Jan 1999, and the cited dissertation was in fact disseminated or published prior to Jan 1999.

Applicants' response has been considered, however, the arguments are not found persuasive because the dissertation by Colleen Mary Toole is available to the public on

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December 14, 1998, which is more than one year before the filing date of parent application (December 21, 1999). Therefore, the rejection is maintained.

New Claim Rejections-Obviousness Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 1-13 and 19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 11 and 13-18 of U. S. Patent 6,649,376.

Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-13 and 19 in the instant application disclose a cell comprising a functional oligomeric phycobiliprotein comprising a fusion protein comprising a functional displayed domain and a functional phycobiliprotein domain, where the fusion protein further comprises (a) a specific binding moiety selected from a streptavidin biotin-binding moiety, a biotinylated or biotinylatable moiety, and an antigen binding immunoglobulin moiety; or (b) a protease cleavage site between the displayed domain and the phycobiliprotein domain; or the cell which comprises a polynucleotide encoding the fusion protein. This is obvious variation in view of claims 11 and 13-18 of the patent which disclose a method of making a fusion protein by expressing a nucleic acid encoding a polypeptide comprising a functional displayed domain and a functional

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phycobiliprotein domain in a cell, and combining the polypeptide with a phycobiliprotein subunit under conditions to form the fusion protein; where the fusion protein may further comprises a linker peptide or a protease cleavage site between the displayed domain and the phycobiliprotein domain. Both sets of claims are directed to a cell comprising a functional oligomeric phycobiliprotein comprising a fusion protein comprising a functional displayed domain and a functional phycobiliprotein domain, and further comprising a specific binding moiety or a protease cleavage site since the cell comprising the fusion protein and the method of making the fusion protein in a cell by expressing a polynucleotide encoding the fusion protein are not patentably distinct. Therefore, claims 1-13 and 19 in instant application and claims 11 and 13-18 of the patent are obvious variations of a cell comprising a functional oligomeric phycobiliprotein comprising a fusion protein comprising a functional displayed domain and a functional phycobiliprotein domain, and further comprising a specific binding moiety or a protease cleavage site.

Claim Objections

8. Claims 14-18 are objected to because the claim is dependent from a rejected claim.

Conclusion

9. Claims 1-13 and 19 are rejected; and claims 14-18 are objected to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.
Primary Patent Examiner

A handwritten signature in black ink, appearing to read 'Chih-Min', followed by a horizontal line and the word 'Primary' written in a cursive script.

**CHIH-MIN KAM
PATENT EXAMINER**

CMK

August 15, 2006